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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,677	06/05/2006	Georgina Jane Clark	DAVI257.001APC	3961

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
11/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/536,677	CLARK ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18 and 27-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III in the reply filed on September 18, 2007 is acknowledged. The traversal is on the ground(s) that all sequences recited in claims 1 and 6 represent molecules with a common structure and a common utility, and as such all fifteen polypeptides and encoding polynucleotides should be searched and examined on the merits (pp. 5-6 of the Response). Applicant's arguments have been fully considered but not found to be persuasive for the following reasons.

2. Upon further consideration, it has been noted that the main invention, product recited in the first claim, is not free of prior art. The first claimed isolated nucleic acid molecules (or fragments thereof) were known in the prior art as indicated by the international search report (application PCT/AU2003/001586), therefore, it cannot serve as a unifying special technical feature. The "special technical features" means those technical features that define a contribution over the prior art. (See M.P.E.P. 1850.)

3. Therefore, the restriction requirement has been reconsidered and new groups of independent and distinct inventions presented in the instant application are as follows:

Groups I to XIII, claim(s) 1-6 and 7-10, in so far as they are drawn to **any one** of thirteen isolated polynucleotide sequences recited therein, vectors and host cells. For example, Invention of Group I consists of claims 1-6 and 7-10only in so far as they encompass an isolated polynucleotide of SEQ ID NO: 1. Invention of Group XIII consists of claims 1-6 and 7-10 only in so far as they encompass an isolated polynucleotide of SEQ ID NO: 25.

Groups XIV to XXIX, claim(s) 6, in so far as they are drawn to **any one** of fifteen polypeptides recited therein.

Groups XXX to XLV, claim(s) 11-14, in so far as they are drawn to antibodies specifically binding to **any one** of fifteen polypeptide sequences recited therein.

Group XLVI, claim(s) 15, drawn to a composition.

Groups XLVII to LXII, claim(s) 16-18, in so far as they are drawn to methods of diagnosis by detecting binding to **any one** of fifteen polypeptide sequences recited therein.

Group LXIII, claim(s) 27, drawn to a composition comprising polypeptides.

Group LXIV, claim(s) 28, drawn to a composition comprising antibodies.

Groups LXV to LXXVIII, claim(s) 29, in so far as they are drawn to methods of diagnosis by detecting binding to **any one** of thirteen nucleotide sequences recited therein.

4. The inventions listed as Groups I to LXXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As explained above, the first named invention is not novel and, therefore, cannot form a "special technical features" to define a contribution over prior art.

Further, 37 C.F.R. § 1.475 (e) specifically states that, "The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim".

In the instant case, the isolated proteins, nucleic acids and antibodies recited in claims 1-14 are different chemical compositions each of which can be made and used without each other. Lack of unity is shown by the fact that these different compositions lack a common utility based upon a shared structural feature lacking from the prior art. Applicant is advised that claims 1 and 6 remain objected as reciting an improper Markush group (language "selected from the group consisting of" followed by recitation of structurally unrelated molecular embodiments), see reasons of record in section 2 of Paper mailed on July 18, 2007. Applicant's arguments that all these sequences define molecules with a common structure and common function are fully considered; however, Applicant failed to identify that common structure which serves for a common utility in nucleic acids of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and 25. Therefore, for purposes of initial examination, the restriction requirement between recited protein, polynucleotide and antibodies as well as methods of using these molecules is proper. However, if during further examination, the common structure of the claimed molecules, which supports the specific and substantial credible utility of these molecules becomes evident and is free of prior art, claims that encompass the molecules that comprise that common structure will be rejoined and fully examined on the merits.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

November 5, 2007